

ECF CASE Document #

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X
MERCK EPROVA AG and MERCK KGaA,

Plaintiffs,

-against-

PROTHERA, INC.,

Defendant.
-----X

08 CV 00035 (RMB)

ANSWER and COUNTERCLAIM

JURY DEMAND

Defendant, ProThera, Inc. ("ProThera") for its Answer and Counterclaim herein, by its attorneys, alleges as follows:

NATURE AND BASIS OF THE ACTION

1. ProThera admits that Merck Eprova AG and Merck KGaA (Collectively "Merck" or "plaintiffs") seeks certain damages and relief enumerated in Paragraph 1. ProThera denies all other allegations of Paragraph 1.

THE PARTIES

2. ProThera admits that Merck Eprova is a corporation; ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the remaining allegations in Paragraph 2, and on that basis denies each and every such remaining allegation.

3. ProThera admits the allegations of Paragraph 3.

JURISDICTION AND VENUE

4. ProThera admits the allegations of Paragraph 4.

5. ProThera admits the allegations of Paragraph 5.

6. ProThera denies it has committed any tortious acts in the State of New York or elsewhere. ProThera admits the remaining allegations of Paragraph 6.

7. ProThera admits the allegations of Paragraph 7.

FACTUAL BACKGROUND

8. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 8, and on that basis denies each and every such allegation.

9. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 9, and on that basis denies each and every such allegation.

10. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 10, and on that basis denies each and every such allegation.

11. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 11, and on that basis denies each and every such allegation.

12. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 12, and on that basis denies each and every such allegation.

13. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 13, and on that basis denies each and every such allegation.

14. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 14, and on that basis denies each and every such allegation.

15. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 15, and on that basis denies each and every such allegation.

16. ProThera denies the allegations of Paragraph 16.

17. ProThera admits the allegations of Paragraph 17.

18. ProThera admits that various diastereoisomers may have different properties, therapeutic effects, etc. ProThera denies there are any such different properties known between the diastereoisomers of 5-methyltetrahydrofolic acid that have any harmful effect on humans.

19. ProThera admits the allegations of Paragraph 19.

20. ProThera admits the allegations of Paragraph 20.

21. The allegations of Paragraph 21 are vague, inconsistent, illogical and incomprehensible, for example because of the terms "naturally", "highly preferable", "predominant" and "unnatural"; thus, ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 21, and on that basis denies each and every such allegation.

22. ProThera admits that L-5-MTHF is a diastereoisomeric form of folate used by cells in the body. ProThera lacks sufficient knowledge and belief as to the meaning of the term

"pure" as used by Merck in Paragraph 22, and on that basis denies each and every such allegation related thereto. Due to this ambiguity, ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the remaining allegations in Paragraph 22, and on that basis denies each and every such remaining allegation.

23. ProThera denies that D-5-MTHF competes with the uptake and activity of L-5-MTHF, and ProThera denies the allegations of Paragraph 23.

24. ProThera has previously relied on Merck's representations that Merck's L-5-MTHF complies with all FDA requirements but ProThera lacks independent knowledge of such compliance and thus lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 24, and on that basis denies each and every such allegation.

25. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 25, and on that basis denies each and every such allegation.

26. ProThera denies the allegations of Paragraph 26.

27. ProThera denies the allegations of Paragraph 27.

28. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 28, and on that basis denies each and every such allegation.

29. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 29, and on that basis denies each and every such allegation.

30. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 30, and on that basis denies each and every such allegation.

31. Presuming that "affiliated" indicates some sort of common ownership, ProThera admits that it is not affiliated with Merck.

32. ProThera admits the allegations of Paragraph 32.

33. ProThera admits the allegations of Paragraph 33.

34. ProThera admits that it sells dietary supplements containing the dietary ingredient 5-MTHF which is in a diastereoisomeric mixture. ProThera denies the remaining allegations of Paragraph 34.

35. ProThera denies the allegations of Paragraph 35 including that ProThera denies any mislabeling.

36. ProThera admits the allegations of Paragraph 36.

37. ProThera admits on March 16, 2006 it received a termination dated March 14, 2006 and admits the termination was effective as of August 14, 2006 for ProThera to cease sale or promotion of product containing METAFOLIN brand L-5-MTHF the allegations of Paragraph 37.

38. ProThera admits the allegations of Paragraph 38 except if "indicated" means "assured" or "guaranteed" then ProThera denies it indicated its inventory would be depleted by about September 2006; ProThera estimated its inventory would be depleted by about September 2006.

39. ProThera denies the allegations of Paragraph 39 because the September 2006 was an estimate not an assurance.

40. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 41 relating to any alleged testing Merck may have done, and on that basis denies such allegations. ProThera denies the remaining allegations of Paragraph 40.

41. ProThera denies the allegations of Paragraph 41.

42. ProThera admits Merck sent it a letter relating to L-5-MTHF and dated October 8, 2007. ProThera denies the remaining allegations of Paragraph 42.

43. ProThera denies each and every allegation in Paragraph 43.

44. ProThera denies the allegations of Paragraph 44 except that ProThera admits that its diastereoisomeric mixture of L-5-MTHF and D-5-MTHF is a diastereoisomeric mixture and that it has knowledge that its diastereoisomeric mixture of L-5-MTHF and D-5-MTHF is a diastereoisomeric mixture.

45. ProThera denies it stated in a March 29, 2007 letter that the L-5-MTHF it uses "is not 'chirally pure but is a racemic mixture of the two optical isomers.'" ProThera admits that in a March 29, 2007 letter to Mr. Beat Leber of the Mattson Jack Group it stated, "[ProThera] uses synthetically produced 5MTHF that is not chirally pure (i.e., our 5MTHF is a racemic mixture). Accordingly, it appears to us that we do not infringe." ProThera admits the remaining allegations in Paragraph 45.

46. ProThera denies the allegations in Paragraph 46.

47. ProThera admits its products contain genuine L-5-MTHF. ProThera denies the remaining allegations in Paragraph 47.

48. ProThera admits and denies the allegations of paragraph 48 in accordance with its admissions and denials above to the extent they are re-asserted by Merck in paragraph 48. ProThera admits it sells its products both inside and outside the United States and in the State of New York.

49. ProThera denies the allegations in Paragraph 49.

50. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 50, and on that basis denies each and every such allegation.

51. ProThera denies the allegations in Paragraph 51.

52. ProThera admits that the L-5-MTHF that it uses is of the highest quality. Otherwise, ProThera denies the allegations of Paragraph 52.

53. ProThera admits that its L-5-MTHF is genuine L-5-MTHF and therefore competes with other products containing genuine L-5-MTHF.

54. The allegations of Paragraph 54 are vague, inconsistent, illogical and incomprehensible, for example due to the completely speculative language "will have" and "could compete"; thus, ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 54, and on that basis denies each and every such allegation.

55. The allegations of Paragraph 55 are vague, inconsistent, illogical and incomprehensible, for example due to the completely speculative language "could expose"; thus, ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 55, and on that basis denies each and every such allegation.

56. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 56, and on that basis denies each and every such allegation.

57. ProThera denies the allegations of Paragraph 57.

COUNT I

ALLEGED FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)

58. ProThera incorporates herein and realleges, as if fully set forth in this Paragraph, the responses to Paragraphs 1 through 57 above, inclusive.

59. ProThera denies the allegations in Paragraph 59.

60. ProThera denies the allegations in Paragraph 60.

61. ProThera denies the allegations in Paragraph 61.

62. ProThera denies the allegations in Paragraph 62.

COUNT II

ALLEGED CONTRIBUTORY FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)

63. ProThera incorporates herein and realleges, as if fully set forth in this Paragraph, the responses to Paragraphs 1 through 62 above, inclusive.

64. ProThera denies the allegations in Paragraph 64.

65. ProThera denies the allegations in Paragraph 65.

66. ProThera denies the allegations in Paragraph 66.

67. ProThera denies the allegations in Paragraph 67.

68. ProThera denies the allegations in Paragraph 68.

69. ProThera denies the allegations in Paragraph 69.

70. ProThera denies the allegations in Paragraph 70.

COUNT III

ALLEGED CONTRIBUTORY FEDERAL TRADEMARK INFRINGEMENT IN VIOLATION OF SECTION 32(1) OF THE LANHAM ACT, 15 U.S.C. § 1114(1)

71. ProThera incorporates herein and realleges, as if fully set forth in this Paragraph, the responses to Paragraphs 1 through 70 above, inclusive.

72. ProThera denies the allegations in Paragraph 72.

73. ProThera denies the allegations in Paragraph 73.

74. ProThera denies the allegations in Paragraph 74.

75. ProThera denies the allegations in Paragraph 75.

76. ProThera denies the allegations in Paragraph 76.

COUNT IV

ALLEGED FEDERAL TRADEMARK DILUTION IN VIOLATION OF SECTION 43(c) OF THE FEDERAL DILUTION ACT OF 1995, 15 U.S.C. § 1125(a)

77. ProThera incorporates herein and realleges, as if fully set forth in this Paragraph, the responses to Paragraphs 1 through 76 above, inclusive.

78. ProThera denies the allegations in Paragraph 78.

79. ProThera denies the allegations in Paragraph 79.

80. ProThera denies the allegations in Paragraph 80.

81. ProThera denies the allegations in Paragraph 81.

82. ProThera denies the allegations in Paragraph 82.

83. ProThera denies the allegations in Paragraph 83.

COUNT V

ALLEGED FEDERAL UNFAIR COMPETITION IN VIOLATION OF SECTION 43(a)(1)(A) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(A)

84. ProThera incorporates herein and realleges, as if fully set forth in this Paragraph, the responses to Paragraphs 1 through 83 above, inclusive.

85. ProThera denies the allegations in Paragraph 85.

86. ProThera denies the allegations in Paragraph 86.

87. ProThera denies the allegations in Paragraph 87.

88. ProThera denies the allegations in Paragraph 88.

89. ProThera denies the allegations in Paragraph 89.

90. ProThera denies the allegations in Paragraph 90.

91. ProThera denies the allegations in Paragraph 91.

COUNT VI

ALLEGED COMMON LAW UNFAIR COMPETITION

92. ProThera incorporates herein and realleges, as if fully set forth in this Paragraph, the responses to Paragraphs 1 through 91 above, inclusive.

93. ProThera denies the allegations in Paragraph 93.

94. ProThera denies the allegations in Paragraph 94.

95. ProThera denies the allegations in Paragraph 95.

96. ProThera denies the allegations in Paragraph 96.

97. ProThera denies the allegations in Paragraph 97.

98. ProThera denies the allegations in Paragraph 98.

COUNT VII

ALLEGED TRADEMARK DILUTION IN VIOLATION OF N.Y. GEN. BUS. LAW §

360(I)

99. ProThera incorporates herein and realleges, as if fully set forth in this Paragraph, the responses to Paragraphs 1 through 98 above, inclusive.

100. ProThera lacks sufficient knowledge and information to form a belief concerning the truth of the allegations in Paragraph 100, and on that basis denies each and every such allegation.

101. ProThera denies the allegations in Paragraph 101.

102. ProThera denies the allegations in Paragraph 102.

103. ProThera denies the allegations in Paragraph 103.

104. ProThera denies the allegations in Paragraph 104.

COUNT VIII

ALLEGED DECEPTIVE TRADE PRACTICES IN VIOLATION OF N.Y. GEN. BUS.

LAW § 349(h)

105. ProThera incorporates herein and realleges, as if fully set forth in this Paragraph, the responses to Paragraphs 1 through 104 above, inclusive.

106. ProThera denies the allegations in Paragraph 106.

107. ProThera denies the allegations in Paragraph 107.

108. ProThera denies the allegations in Paragraph 108.

109. ProThera denies the allegations in Paragraph 109.

110. ProThera denies the allegations in Paragraph 110.

COUNT IX

ALLEGED FALSE ADVERTISING IN VIOLATION OF N.Y. GEN. BUS. LAW §

350(e)(3)

111. ProThera incorporates herein and realleges, as if fully set forth in this Paragraph, the responses to Paragraphs 1 through 110 above, inclusive.

112. ProThera denies the allegations in Paragraph 112.

113. ProThera denies the allegations in Paragraph 113.

114. ProThera denies the allegations in Paragraph 114.

115. ProThera denies the allegations in Paragraph 115.

116. ProThera denies the allegations in Paragraph 116.

JURY DEMAND

117. ProThera demands a trial by jury of all jury issues.

AFFIRMATIVE DEFENSES

118. ProThera repeats and realleges Paragraphs 1 through 117 as though set forth in the following affirmative defenses.

I. FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

119. The Complaint fails to allege sufficient facts to state a claim upon which relief can be granted.

COUNTERCLAIM: DECLARATORY JUDGMENT

I. THE PARTIES

120. Counterclaimant ProThera is a Nevada corporation with its principal place of business at 10439 Double R Boulevard, Reno, Nevada 89521. ProThera is a manufacturer, distributor and supplier of nutritional dietary supplements, and sells and distributes its products worldwide, including within the United States and in the state of New York.

121. On information and belief, Merck Eprova is a Swiss corporation with a principal place of business at Im Laternenacker 5, CH-8200 Schaffhausen, Switzerland. Merck KGaA, Darmstadt, is a German association by limited shares, with a principal place of business at Frankfurter Str. 250, D-64293 Darmstadt, Germany. On information and belief, Merck Eprova is the Swiss affiliate of Merck KGaA and manufacturers numerous pharmaceutical and other products.

II. REQUEST FOR DECLARATORY JUDGMENT

122. As described in Paragraphs 1-116 and in the Prayer for Relief of the Complaint filed by Merck on January 3, 2008, with the United States District Court for the Southern District of New York, Case No. 08 CV 00035, Merck has accused ProThera of multiple improper acts relating to alleged labeling of certain of ProThera's products for containing genuine L-5-MTHF and "pure" L-5-MTHF as well as for contributorily infringing Merck's METAFOLIN trademarks by inducing and encouraging ProThera's distributors and customers to wrongfully use Merck's METAFOLIN trademarks.

123. Merck's Complaint creates ripe and justiciable issues for this Court.

124. As set forth in ProThera's Answer above, ProThera denies that it is engaged in any wrongful conduct.

125. The plain, ordinary meaning of "genuine" is "real," for example as defined at Dictionary.com, <http://dictionary.reference.com/search?q=genuine&r=66>:

1. possessing the claimed or attributed character, quality, or origin; not counterfeit; authentic; real: *genuine sympathy*; *a genuine antique*.
2. properly so called: *a genuine case of smallpox*.

126. "L-5-methyltetrahydrofolic acid", also known as the abbreviation "L-5-MTHF", is the scientifically correct term to describe a particular chemical compound, namely, L-5-methyltetrahydrofolic acid.

127. "L-5-methyltetrahydrofolic acid", also known as the abbreviation "L-5-MTHF", is the generic term used to describe a particular type of folic acid, namely, L-5-methyltetrahydrofolic acid.

128. The term "L-5-methyltetrahydrofolic acid", by itself, when used to indicate the presence of genuine, i.e., real, L-5-methyltetrahydrofolic acid in a composition does not indicate whether such L-5-methyltetrahydrofolic acid is present with or without the diastereoisomer D-5-methyltetrahydrofolic acid.

129. The term "L-5-methyltetrahydrofolic acid", by itself, when used to indicate the presence of genuine, i.e., real, L-5-methyltetrahydrofolic acid in a composition does not indicate the level of purity of such L-5-methyltetrahydrofolic acid in that composition.

130. Certain of ProThera's products contain genuine, i.e., real, L-5-MTHF.

131. The genuine, i.e., real, L-5-MTHF in ProThera's products is present as part of racemic mixture that also comprises genuine, i.e., real, D-5-MTHF.

132. The "ProThera Compound" identified and complained of in Merck's Complaint comprises genuine, i.e., real, L-5-MTHF (as well as genuine, i.e., real, D-5-MTHF).

133. Merck does not dispute that ProThera's products that Merck identified as containing "ProThera Compound" contain genuine, i.e., real, L-5-MTHF.

134. The labeling, advertising and other consumer documents published by ProThera accurately identify the genuine, i.e., real, L-5-MTHF in its ProThera products by its scientifically accurate name, i.e., L-5-MTHF.

135. The labeling, advertising and other consumer documents published by ProThera accurately identify the genuine, i.e., real, L-5-MTHF in its ProThera products by its generic name, i.e., L-5-MTHF.

136. The labeling, advertising and other consumer documents published by ProThera accurately identify the genuine, i.e., real, L-5-MTHF in its ProThera products as being genuine, i.e., real, L-5-MTHF.

137. Merck filed its Complaint with knowledge that ProThera's labeling, advertising and other consumer documents described in paragraphs 135-136 above accurately describe the genuine, i.e., real, L-5-MTHF in its ProThera products by its scientifically accurate name, i.e., L-5-MTHF.

138. Merck filed its Complaint with knowledge that ProThera's labeling, advertising and other consumer documents described in paragraphs 135-136 above accurately describe the genuine, i.e., real, L-5-MTHF in its ProThera products by its generic name, i.e., L-5-MTHF.

139. Merck filed its Complaint with knowledge that ProThera's labeling, advertising and other consumer documents described in paragraphs 135-136 above accurately describe the genuine, i.e., real, L-5-MTHF in its ProThera products as being genuine, i.e., real, L-5-MTHF.

140. ProThera has never described the genuine, i.e., real, L-5-MTHF in the "ProThera Compound" identified and complained of in Merck's Complaint as "pure" L-5-MTHF.

141. ProThera has never used the word "pure" to describe the genuine, i.e., real, L-5-MTHF in the "ProThera Compound" identified and complained of in Merck's Complaint.

142. On information and belief, Merck has no evidence of ProThera describing the genuine, i.e., real, L-5-MTHF in the "ProThera Compound" identified and complained of in Merck's Complaint as "pure L-5-MTHF".

143. On information and belief, Merck has no evidence of ProThera using the word "pure" to describe the genuine, i.e., real, L-5-MTHF in the "ProThera Compound" identified and complained of in Merck's Complaint.

142. On information and belief, ProThera's customers have never described the genuine, i.e., real, L-5-MTHF in the "ProThera Compound" identified and complained of in Merck's Complaint as "pure" L-5-MTHF.

143. On information and belief, ProThera's customers have never used the word "pure" to describe the genuine, i.e., real, L-5-MTHF in the "ProThera Compound" identified and complained of in Merck's Complaint.

144. The allegations in Merck's Complaint, for example in paragraphs 34, 35, 40, 43, 46, 47, 52, 59, 60, 64, 65, 66, 85, 106, and 112, that ProThera's labels and/or material available on its web-site advertise that Prothera's Compound contains "pure L-5-MTHF" are false.

145. On information and belief, the allegations in Merck's Complaint, for example in paragraphs 50, 51, that ProThera's customer's labels and/or material available on their web-sites advertise that Prothera's Compound contains "pure L-5-MTHF" are false.

146. On information and belief, Merck knows that the allegations in Merck's Complaint, for example in paragraphs 34, 35, 40, 43, 46, 47, 52, 59, 60, 64, 65, 66, 85, 106, and 112, that ProThera's labels and/or material available on its web-site advertise that Prothera's Compound contains "pure L-5-MTHF" are false.

147. On information and belief, Merck knows that the allegations in Merck's Complaint, for example in paragraphs 50, 51, that ProThera's customer's labels and/or material available on their web-sites advertise that Prothera's Compound contains "pure L-5-MTHF" are false.

148. Triune Wellness and Prescription 2000 are not distributors of ProThera.

149. ProThera has no input nor control over of the advertising, sales, marketing or other business practices of Triune Wellness and Prescription 2000.

150. ProThera has never encouraged, asked or otherwise induced Triune Wellness and Prescription 2000 nor any of its other customers to label or otherwise describe the genuine, i.e., real, L-5-MTHF in the "ProThera Compound" as "pure" L-5-MTHF.

151. ProThera has never encouraged, asked or otherwise induced Triune Wellness and Prescription 2000 nor any of its other customers to improperly use the METAFOLIN marks.

PRAYER FOR RELIEF

WHEREFORE, defendant, ProThera, Inc., prays that this Court enter judgment:

- A. Dismissing with prejudice all the claims of Merck's Complaint.
- B. Declaring that ProThera's accurately describing genuine "L-5-methyltetrahydrofolic acid", also known as the abbreviation "L-5-MTHF", as genuine L-5-methyltetrahydrofolic acid is not wrongful conduct constituting a basis for a cause of action under either Federal or New York State law.
- C. Declaring that ProThera's accurately describing genuine L-5-methyltetrahydrofolic acid by its scientific and generic name, i.e., "L-5-methyltetrahydrofolic acid", is not wrongful conduct constituting a basis for a cause of action under either Federal or New York State law.
- D. Declaring that ProThera's accurately describing a ProThera product as containing L-5-methyltetrahydrofolic acid where such product also contains D-5-methyltetrahydrofolic acid with no statement that the L-5-methyltetrahydrofolic acid is "pure" L-5-methyltetrahydrofolic acid is not wrongful conduct giving rise to a cause of action under either Federal or New York State law.

E. Declaring that ProThera's accurately and generically describing L-5-methyltetrahydrofolic acid as a component of a product is not wrongful and does not constitute a basis for a cause of action under either Federal law or New York State law.

F. That ProThera recover from Merck such damages and attorney's fees relating to defending against Merck's Complaint and pursuing this declaratory judgment action, and such other relief as may be appropriate, under Federal law or the laws of the State of New York.

G. That ProThera have such other and further relief as the Court may deem just and proper.

Dated: New York, New York
March 3, 2008

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